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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,042

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Shigeyoshi Nishino

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04/16/2008

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EXAMINER

MOORE, SUSANNA

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,042	Applicant(s) NISHINO ET AL.	
	Examiner SUSANNA MOORE	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 8, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III in the reply filed on 3/17/2008 is acknowledged. Group III, drawn to a method of making quinazolines, embraced by claims 1-7, 9 and 10 was elected by Applicant. Applicant pointed to no errors in the Examiners analysis of the classification of the different inventions. The requirement is deemed proper and is therefore made **FINAL**.

There are twelve claims pending and nine under consideration. Claims 8, 11 and 12 are currently withdrawn. This is the first action on the merits. The application concerns the process of making substituted quinazoline compounds.

This application contains claims 1-8, 11 and 12, drawn to an invention nonelected with traverse in the paper of 3/17/2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Claim Objections

Claim 9 is objected to because of the following informalities: said claim, which is dependent on claim 1, is not further limiting. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9 and 10 have the phrase “has the meaning as defined above” for many variables, e.g. R^a and R^b , among others. These variables are not defined above, but rather in claim 1. Thus, the phrase is vague.

Claims 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 9 and 10 have the phrase “does not participate in the reaction” for the R^8 variable. However, R^8 does participate in the reaction. It is a leaving group. Thus, the phrase is vague.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Gakhar et. al. (J. Indian Chem. Soc., 1987, 64, 373-375).

The reference teaches the compounds of formula (5), wherein the substitution on the 2-aminophenyl methyl ester is a 1,3-dioxolo, which does not participate in the reaction, with triethylorthoformate (formula 4) and aniline (formula 2) in ethanol, a lower alcohol, at reflux (ethanol refluxes at 78°C). See page 374, the scheme in the left-hand column and the

experimental section on the right-hand side of the same page. Thus, said claims are anticipated by Gakhar et al.

Claims 1, 5-7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rad-Moghadam et. al. (J. Chem. Research, 1998, 11, 702-703).

The reference teaches the compounds of formula (5), wherein anthranilic acid with triethyl orthoacetate (formula 4) and a corresponding amine (formula 2) is heated by microwave. See page 703, left-hand column, second to the last paragraph. Thus, said claims are anticipated by Rad-Moghadam et. al.

Claims 1-5, 7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Tobe et. al. (Bioorg. Med. Chem., 2003, 11, 383-391).

The reference teaches the compounds of formula (5), wherein 2-aminophenyl carboxylic acid with an ammonia solution (formula 2), followed by reaction with trimethylformate (formula 4) in sequential steps at room temperature and cooling, respectively. See page 385, Scheme 2 at the top of the page and page 388, in the left-hand column the third and fourth full paragraphs. The reference does not disclose the solvent in which the ammonia solution was purchased, thus, inherently ammonia solutions can be purchased at Sigma-Aldrich in ethanol. See Aldrich reference. Thus, said claims are anticipated by Tobe et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1624

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being obvious over Nishino et. al. (JP 2003-212862).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not an invention “by another”; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant Application teaches the reaction of compounds of formula (1), anthranilic acids, with compounds of formula (4), trioxo formate acid derivatives, and compounds of formula (2 or 3, corresponding amines) in a lower alcohol with heating (range 40C-200C) which result in the compounds of formula (5), quinazolines.

The reference teaches the process of making of compounds of formula (5), the ammonium salt of the anthranilic acid derivative can be made by reacting anthranilic acid (formula 1) with a solution of ammonia (formula 2) in ethanol, see paragraph 0023 on page 3. Furthermore, the reaction takes place with a formic acid derivative, which triethylorthoformate meets the limitation of a formic acid derivative (formula 4). The reaction is heated, see paragraph 0028, page 3, and can be reacted in ethanol, a lower alcohol, see paragraph 0026, page 3. Thus, said claims are rendered obvious over Nishino et al.

Claims 1-7, 9 and 10 are rejected under 35 U.S.C. 103(a) as being obvious over Nishino et. al. (JP 2003-183262).

The applied reference has common inventors with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The instant Application teaches the reaction of compounds of formula (1), anthranilic acids, with compounds of formula (4), trioxo formate acid derivatives, and compounds of formula (2 or 3, corresponding amines) in a lower alcohol with heating (range 40C-200C) which result in the compounds of formula (5), quinazolines.

The reference teaches the process of making of compounds of formula (5), the ammonium salt of the anthranilic acid derivative can be made by reacting anthranilic acid (formula 1) with a solution of ammonia (formula 2) in ethanol, see paragraph 0025 on page 3.

Furthermore, the reaction takes place with a formic acid derivative, which triethylorthoformate meets the limitation of a formic acid derivative (formula 4). The reaction is heated, see paragraph 0029, page 3, and can be reacted in ethanol, a lower alcohol, see paragraph 0027, page 3. Thus, said claims are rendered obvious over Nishino et al.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned

with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9 and 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7232903. Although the conflicting claims are not identical, they are not patentably distinct from each other because both Applications embrace a method or processing a quinazoline. The only difference between the instant Application and '903 patent is the organic acid, formula (4). However, the '903 patent discloses the use of formic acid derivatives, see column 2, line 14. Thus, the '903 patent renders said claims obvious.

Claims 1-7, 9 and 11 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6, 8, 9, 16-19, 33 and 34 of copending Application No. 10502734. Although the conflicting claims are not identical, they are not patentably distinct from each other because both Applications embrace a method or processing a quinazoline. The only difference between the instant Application and '734 patent is the organic acid, formula (4). However, the '734 disclosure states the use of formic acid derivatives, see page 6, line 25. Thus, the '734 Application renders said claims obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSANNA MOORE whose telephone number is (571)272-9046. The examiner can normally be reached on M-F 8:00-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susanna Moore/
Examiner, Art Unit 1624

**/James O. Wilson/
Supervisory Patent Examiner, Art Unit 1624**